

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of Elrod et al.

:Group Art Unit: Not Yet known

Application No.: 10/581,977

:Examiner: Not Yet known

Filed: December 10, 2006

:Docket No. 53524AUSM1

For: USE OF CATHEPSIN S INHIBITORS FOR TREATING AN IMMUNE RESPONSE  
CAUSED BY ADMINISTRATION OF A SMALL MOLECULE THERAPEUTIC OR  
BIOLOGIC

Mail Stop: PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 CFR §1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references cited from a foreign patent office on the attached form PTO-1449 (copies enclosed).

As to any reference supplied, Applicants do not admit that it is "prior art" under 35 U.S.C. §102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. §1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with Applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, Applicants believe that their invention is patentable.

This Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits as described in 37 CFR 1.97(b). Therefore, it is believed that no fee is required under 37 CFR 1.97(b)(3). However, the Commissioner is hereby authorized to charge any additional fees required to facilitate the filing of this application to deposit account 02-2117. This is, however, not authorization to charge the issue fee.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully Submitted,  
BERLEX BIOSCIENCES  
Customer No. 27586

*Jacqueline S Larson*

Jacqueline S. Larson (Reg. No. 30,279)  
Patent Attorney for Applicants

Date: Oct. 13, 2006

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FORM PTO-1449 (REV.7-80)  <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>53524AUSM1</b>	APPLICATION NO. <b>10/581,977</b>
	APPLICANTS <b>Elrod et al.</b>			
	FILING DATE <b>December 10, 2004</b>		GROUP ART UNIT <b>Not Yet Known</b>	

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		US 6,608,030	Aug. 19. 03	Ploegh et al.			
		US 7,101,880	Sept. 05. 06	Graupe et al.			
		US2005/0182096	Aug. 18. 05	Link et al			
		US2003/232864	Dec. 18. 03	Link et al			

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
		WO02/20485	Mar. 14. 02	PCT		
		WO03/029200	Apr. 10. 03	PCT		
		WO02/20002	Mar. 14. 02	PCT		
		WO04/083182	Sept. 30. 04	PCT		
		WO04/028521	Apr. 08. 04	PCT		
		WO05/028429	Sept. 17. 04	PCT		
		WO06/034006	Sept. 16. 05	PCT		
		WO04/00838	Dec. 31. 03	PCT		
		WO04/108661	Dec. 16. 04	PCT		
		WO02/098850	Dec. 12. 02	PCT		
		WO05/028454	Sept. 17. 04	PCT		
		WO05/058348	Dec. 10. 04	PCT		
		WO05/063742	Dec. 22. 04	PCT		
		WO05/074904	Jan. 31. 05	PCT		
		WO06/060494	Dec. 01. 05	PCT		
		WO00/55144	Sept. 21.00	PCT		
		WO01/19796	Mar. 22. 01	PCT		
		WO03/024924	Mar. 27.03	PCT		
		WO04/033445	Apr. 22. 04	PCT		

FORM PTO-1449 (REV.7-80)		U. S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>53524AUSM1</b>		APPLICATION NO. <b>10/581,977</b>	
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>				APPLICANTS <b>Elrod et al.</b>			
				FILING DATE <b>December 10, 2004</b>		GROUP ART UNIT <b>Not Yet Known</b>	
		WO03/097617	Nov. 27. 03	PCT			
		WO06/102423	Mar. 23. 06	PCT			
		WO01/19816	Mar. 22. 01	PCT			
		WO00/51998	Sept. 8. 00	PCT			
		WO02/069901	Sept. 12. 02	PCT			
		WO06/102535	Mar. 22. 06	PCT			
		WO06/060810	Dec. 01. 05	PCT			
		WO06/034004	Sept. 16. 05	PCT			
		WO06/102243	Mar. 17. 06	PCT			
		EP 1 516 877	Mar. 23. 05	EP			
		EP 0 623 627	Nov. 09 .94	EP			
	7	Riese et al., "Cathepsin S Activity Regulates Antigen Presentation and Immunity." <i>Journal of Clinical Investigation</i> , Pages 2351-2363, June 1998.					
	8	Saegusa et al., "Cathepsin S Inhibitor Prevents Autoantigen Presentation and Autoimmunity." <i>Journal of Clinical Investigation</i> , Vol. 110, No.3, Pages 361-369, August 2002.					
EXAMINER				DATE CONSIDERED			
<b>* EXAMINER:</b> Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applican(s).							

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/581,977
	Filing Date	December 10, 2004
	First Named Inventor	Elrod et al.
	Art Unit	Not Yet Known
	Examiner Name	Not Yet Known
Total Number of Pages in This Submission	Attorney Docket Number	53524AUSM1

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO-1449 With Cited Refs. Return Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Berlex Biosciences.		
Signature	<i>Jacqueline S. Larson</i>		
Printed name	Jacqueline S. Larson		
Date	Oct. 13, 2004	Reg. No.	30,279

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature	<i>A. M. Babb</i>		
Typed or printed name	Alishia L. Rowe-Babb	Date	10.13.06

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Inventor:** Elrod et al.  
**Case No.:** 5352<sup>4</sup>AUSM1  
**Serial No.:** 10/581,977  
**Filing Date:** December 10, 2004  
**Attorney or Agent:** Jacqueline S. Larson  
**Document(s):** Transmittal Form (1page)  
Form-1449 (2page)  
IDS w/ cited refs

**Date Sent to USPTO: October 13, 2006**

**Via First Class Mail**